

CHAPTER NO. 866

SENATE BILL NO. 3738

By Beavers

Substituted for: House Bill No. 3844

By Rowland

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, relative to the generic substitution of prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 53-10-208, is amended by deleting the section in its entirety and substituting instead the following new language:

Section 53-10-208. (a) In making substitutions as allowed by this part, the pharmacist may use drugs and drug products manufactured within the territorial limits of any one of the states of the United States, or of any other country, if such products have been approved by the Federal Food and Drug Administration and have been given an "A" therapeutic equivalent rating by the Federal Food and Drug Administration in the agency's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", also known as the "Orange Book". "A" rated drug products are those that the Federal Food and Drug Administration considers to be therapeutically equivalent to other pharmaceutically equivalent products, including, but not limited to, drug products for which:

(1) There are no known or suspected bioequivalence problems and are designated "AA", "AN", "AO", "AP" or "AT", depending on the dosage form; or

(2) Actual or potential bioequivalence problems have been resolved with adequate in vivo or in vitro evidence supporting bioequivalence and are designated "AB".


(b) The provisions of this section shall not apply to generic drugs and drug products that have not been rated.

(c) For those drugs that have not been evaluated and rated for bioequivalency by the United States Food and Drug Administration, pharmacists are permitted to use their professional judgment in selecting a generic product for substitution.

SECTION 2. This act shall take effect upon becoming a law, the public welfare requiring it.

Passed: May 25, 2006


JOHN S. WILDER
SPEAKER OF THE SENATE


JIMMY NAIFEH, SPEAKER
HOUSE OF REPRESENTATIVES

APPROVED this 5th day of June 2006


PHIL BREDESEN, GOVERNOR